OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

Legislative Budget Office

H.B. 558
134th General Assembly

Final Fiscal Note & Local Impact Statement

Click here for H.B. 558's Bill Analysis

Primary Sponsors: Reps. Roemer and Jordan

Local Impact Statement Procedure Required: No

Jamie Doskocil, Division Chief, and other LBO staff

Highlights

- The State Board of Pharmacy will incur minimal one-time costs to draft and update administrative rules governing its existing Drug Repository Program and drug delivery devices.
- The State Board of Pharmacy will experience a slight decrease in terminal distributor of dangerous drugs license revenue, which is credited to the Occupational Licensing and Regulatory Fund (Fund 4K90), due to the fee exemption of charitable pharmacies that participate in the Drug Repository Program. Licensing would still be required and the Board would still oversee and inspect the participating pharmacies.
- The bill generally expands existing overdose reversal drug access authority, including by authorizing access for all persons and government entities to purchase, possess, distribute, dispense, personally furnish, sell, or otherwise obtain or provide an overdose reversal drug and any instrument or device to administer it. If additional state or government entities choose to engage in these activities due to the bill, the entities could realize costs for doing so.

Detailed Analysis

Drug Repository Program

The bill modifies the state's Drug Repository Program managed by the State Board of Pharmacy. Most notably, the bill:

- Exempts charitable pharmacies, nonprofit clinics, and hospitals from current law's general prohibition on accepting or distributing drugs not in their original sealed and tamper-evident unit dose packaging;

- Exempts charitable pharmacies, nonprofit clinics, and hospitals from the existing prohibition on reselling drugs donated to the program, by authorizing those entities to make occasional sales of donated drugs at wholesale;
- Extends the authority to distribute drugs under the program to licensed health professionals authorized to prescribe drugs;
- Eliminates the requirement that the Board consult with the Director of Health when adopting rules; and
- Exempts charitable pharmacies that participate in the program from the requirement to pay licensure and renewal fees that otherwise apply to operate as a terminal distributor of dangerous drugs.

The Drug Repository Program manages the collection and distribution of drugs donated or given by pharmacies, drug manufacturers, health care facilities, and others to Ohio residents who meet eligibility standards established by the Board. The bill's changes essentially expand the program's scope by allowing for (1) the participation of more organizations and entities and (2) the collection and distribution of a broader array of drugs.

The Board will be required to update the administrative rules relating to the program, including a form to be signed when making a donation. The costs would be administrative in nature, occur one-time, and likely be absorbed in the normal day-to-day operations using existing staff and resources. The staff of the Board do not anticipate any additional operating expenses regardless of the number of organizations and entities that may choose to participate.[1] By eliminating the requirement that the Board consult with the Director of Health when adopting rules governing the program, the bill appears to largely codify current practice, as the Department of Health's role in the program currently is extremely limited.

There will be a slight decrease in terminal distributor of dangerous drugs licensure revenue, which is credited to the Occupational Licensing and Regulatory Fund (Fund 4K90), due to the fee exemption (shown in the table below) of charitable pharmacies that participate in the program. Currently, there are three charitable pharmacies operating in Ohio, all currently licensed by the Board. The number of additional organizations and entities that would opt to participate in the program because of the bill is unknown. Licensing would still be required and the Board would still oversee and inspect the participating pharmacies.

Terminal Distributor of Drug Distributors (TDDD) License Fee Schedule	
Class	**Fee**
Category II or Limited Category II	$320
Category III or Limited Category III	$440

[1] The bill will apply to Ohio's Federally Qualified Health Centers (FQHCs, or community health centers).

Terminal Distributor of Drug Distributors (TDDD) License Fee Schedule	
Class	**Fee**
Professional Association, Corporation, Partnership, or Limited Liability Company Organized to Practice Veterinary Medicine	$120
Solo Practitioner, Sole Shareholder, or Dentist	$120
EMS Satellite Locations	$120
Late Renewal Penalty	$110

Overdose reversal drug access

The bill generally expands overdose reversal drug access authority, including by authorizing access for all persons and government entities to purchase, possess, distribute, dispense, personally furnish, sell, or otherwise obtain or provide an overdose reversal drug and any instrument or device to administer it, if certain conditions are met. These conditions include the following: the overdose reversal drug is in its original manufacturer's packaging, its packaging contains the manufacturer's instructions for use, and it is stored in accordance with a manufacturer's or a distributor's instructions. As part of this general expansion, a number of additional provisions are also included. For example, the bill authorizes persons and government entities to obtain and maintain a supply of overdose reversal drugs for use in emergency situations and for distribution through an automated mechanism. The bill also exempts all persons and government entities that possess overdose reversal drugs from the requirement to be licensed as a terminal distributor of dangerous drugs and specifically exempts health care practitioners from the licensure requirement to maintain overdose reversal drugs for use in personally furnishing supplies. Additionally, the bill provides various immunities, such as a person or government entity that exercises the authority granted by the bill not being subject to administrative action or criminal prosecution and not being liable for civil damages arising from exercising that authority. Furthermore, the bill modifies existing law related to who may authorize a pharmacist or pharmacy intern to dispense overdose reversal drugs without a prescription pursuant to a protocol by eliminating the authority of boards of health to authorize dispensing pursuant to a protocol and expanding the authority to physician assistants and advanced practice registered nurses (the bill maintains physicians' current authority). Additionally, the bill expressly authorizes an individual to administer an overdose reversal drug if the individual is in a position to assist another who is apparently experiencing an opioid-related overdose. Finally, the bill specifies that a state agency or board is not subject to review by the Common Sense Initiative Office and is not required to transmit a business impact analysis to the Office if amending a rule solely to reflect the change of using the term "overdose reversal drug" instead of "naloxone."

Current law does provide for the distribution of an overdose reversal drug in various circumstances. Thus, the fiscal impact of this bill will depend on the extent to which it results in additional state or government entities choosing to engage in its distribution, purchase, etc. If this occurs, then a state or local government entity could realize costs. If state or local public health programs or plans reimburse for overdose reversal drugs that are provided to individuals

without a prescription, there could be costs if access is expanded. In addition, if any entities currently licensed as a terminal distributor of dangerous drugs are exempt from licensure under the bill, the Pharmacy Board could realize a loss of future revenue. However, the Pharmacy Board currently offers a number of exemptions in these situations, so it anticipates that any impact would be minimal. Lastly, the provisions related to immunity from criminal prosecutions and civil liability will decrease court costs to the extent that cases would have been prosecuted under current law.

Pharmacist authority to modify prescriptions

The bill authorizes a pharmacist to modify a drug's prescription to also include a drug delivery device, if the pharmacist determines that the device is necessary for the drug's administration and under the terms of a health benefit plan. The Board of Pharmacy may adopt rules to implement these provisions. Any costs for the Board to adopt associated administrative rules would be negligible and likely absorbed in the routine rule-adopting schedule already observed by the Board and its staff.

Pediatric transition care programs

The bill eliminates licensure for pediatric respite care programs that provide only pediatric transition care, and instead requires registration for those programs. Under the bill, the Department of Health is required to adopt rules relating to the registration of pediatric transition care programs, including establishing fees for initial registration, renewals, and inspections. The bill prohibits initial and renewal registration fees from exceeding $600 during the three-year renewal cycle and prohibits inspection fees from exceeding $1,750. However, subject to the approval of the Controlling Board, the Department may establish fees in excess of these maximum amounts, provided that the fees do not exceed these amounts by more than 50%. Current law requires the same fee amounts for licensure as a pediatric respite care program. If a pediatric transition care program is currently licensed as a pediatric respite care program, there should be no revenue change. If additional entities are registered, then there could be additional revenue and costs. The Department will experience a negligible increase in administrative costs to adopt rules.

Hypertrophic Cardiomyopathy Awareness Day

The bill designates the fourth Wednesday of February as "Hypertrophic Cardiomyopathy Awareness Day." This provision has no direct fiscal effect on the state or political subdivisions, as it does not require any action on the part of either.

Bleeding Disorders Awareness Month

The bill designates the month of March as "Bleeding Disorders Awareness Month." This provision has no direct fiscal effect on the state or political subdivisions, as it does not require any action on the part of either.

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